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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/722,737
Filing Date: November 25, 2003
Appellant(s): GALER, BRADLEY S.

Paul Carango and T. Daniel Christenbury
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/1/10 appealing from the Office action mailed 6/9/10. (Note that Appellent states that the Appeal Brief is submitted in response

to the Official Office Action dated December 28, 2009. However, the Office Action filed on 12/28/09 is a non-final Action and the Official Office Action filed on 6/9/10 is the FINAL Office Action.)

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 1-11.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office

action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5411738	Hind	5-1995
20040101582	Wolicki	5-2004

Rowbotham et al. (Brain 1996, 119, 347-354; IDS filed on 11/3/09)

Medical Encyclopedia: Neuralgia: [online] retrieved from: http://www.him.nih.gov/medlineplus/ency/article/001407.htm on 1/12/09; 9/7/06; 4 pages.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hind (US 5411738) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia and Rowbotham et al. (Brain 1996, 119, 347-345) (Applicant supplied IDS filed on 11/3/09).

Hind discloses methods for treating nerve injury such as post-herpetic neuralgia with topical application of lidocaine to the skin ***at the site of the pain*** (Abstract and claims 1-8). It is inherent in the method of Hind that a patient is identified as having neuropathically induced negative sensory phenomena and the location is identified because, *as evidenced by* Rowbotham et al., the pain and negative sensory phenomena are intimately tied together. Perfoming the method of Hind inherently treats all symptoms, including numbness, of the disorder. It must. Hind uses the same compound as instantly claimed and it is well known that: "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The teachings of Rowbotham et al. clearly state that in post herpatic neuralgia, patients "***demonstrated deficits in the perception of single gentle touches, pinprick, heat and cold which were greatest in the centre of the painful area and faded toward the boundary between involved and normal skin***." (page 347, right column; Examiner added emphasis). Thus the patients had pain and loss of sensory perception simultaneously in the same location and, in the method of Hind, application of lidocaine to the skin at the site of the pain would simultaneously treat the pain and negative sensory phenomena. The Examiner is interpreting "deficits in the perception of

single gentle touches" to mean numbness because Applicant states that numbness is a sensory deficit such as a decreased ability to feel light touch (page 1, [0002, 0011] of the instant specification). In addition, *as evidenced by* MedlinePlus Medical Encyclopedia: Neuralgia, which is also known as postherpetic neuralgia, the symptoms include pain and **numbness** of the affected skin area (See symptoms pages 1-2 of 4). *Therefore, it is the Examiner's position that simply by identifying a patient with post herpatic neuralgia, where one of the symptoms is numbness, then numbness is also inherently identified and treated by application of the lidocaine to decrease the numbness in the patient. It is simply inherent in the method of Hind.* Numbness is a neuropathically-induced negative sensory phenomena (See [0011] pages 3-4 of the instant specification). Therefore, the method of Hind inherently treats any neuropathically-induced negative sensory phenomena, such as numbness, because it is a symptom and associated with the disorder and instant claims 1-4 and 9-11 are anticipated. Hind discloses applying a patch which anticipates instant claim 5 (claims 2-6). Hind discloses from about 1-20% lidocaine which anticipates instants claim 6 and 7 (claim 5). Hind discloses a lidocaine patch with a non-woven polyester backing which anticipates instant claim 8 (column 15, lines 11-16 and claim 3). Hind discloses a method in column 15, lines 11-26:

> Study Drug and Placebo
> Lidocaine patches (Lidoderm Patch) contain an adhesive of 5% lidocaine base (700 mg/patch), water, glycerin, D-sorbitol, sodium polyacrylate, sodium carboxymethylcellulose, propylene glycol and other ingredients on a non-woven polyester backing. Vehicle placebo patches are identical except for the absence of lidocaine. The size of a single patch is 10×14 cm.
> Patch Application
> Prior to patch application, the painful area to be treated was marked and then photographed based on the subject's report of (1) the borders of the area of sensory abnormality, and (2) the area of greatest pain. Up to 3 patches were applied to cover the area of greatest pain as fully as possible within the limit of 420 cm^2 Of patch area.

Since 'backing' is being interpreted to mean a cover and any numbness is inherently treated by the method and instant claims 1-11 are anticipated as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hind (US 5411738 (IDS filed on 4/30/04) in view of Wolicki (US 2004/0101582) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia and Rowbotham et al. (Brain 1996, 119, 347-345) (Applicant supplied IDS filed on 11/3/09).

Applicant claims a method for treating neuropathically-induced negative sensory phenomena comprising applying an anesthetic topically to the skin of a patient suffering from neuropathic negative sensory phenomena at or near the locus of the negative sensory phenomena.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Hind, Rowbotham et al., and MedlinePlus are discussed in detail above and those discussions are hereby incorporated by reference.

Wolicki teaches in claim 6 the equivalence of various benzoic acid derivatives for the treatment of neuropathy:

> 6. The topical composition of claim 2, wherein said additional ingredient is selected from the group consisting of: capsaicin, lidocaine, bupivacaine, mepivacaine, ropivacaine, tetracaine, etidocaine, chloroprocaine, prilocaine, procaine, benzocaine, dibucaine, dyclonine hydrochloride, pramoxine hydrochloride, benzocaine, and proparacaine.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Hind is that Hind do not expressly teach various benzoic acid derivatives in the method. This deficiency in Hind is cured by the teachings of Wolicki.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add other benzoic acid derivatives, as suggested by Wolicki, to the method of Hind and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art teaches the benzoic acid derivatives to be equivalent in methods of treating neuropathy. The expected result remains treatment of the neuropathy.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(10) Response to Argument

With respect to the 102(b) rejection, Appellent asserts that the Examiner has failed to consider and is simply ignoring all the elements/recitations in the claims. Respectfully, the Examiner cannot agree. As set forth in the Final Office Action, it is inherent in the method of Hind that a patient is identified as having neuropathically induced negative sensory phenomena and the location is identified because, *as evidenced by* Rowbotham et al., the pain and negative sensory phenomena are intimately tied together. Performing the method of Hind inherently treats all symptoms, including numbness, of the disorder. It must. Hind uses the same compound as instantly claimed and it is well known that: "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, Hind teaches that: "PHN patients nearly always have a sensory deficit in the region obtained (column 1, lines 28-30). ***Thus Hind recognized and includes those patients with sensory deficits***. From MPEP 2112 IV, the principle of law states: "*To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner has shown that pain and negative sensory

phenomena are coextensive and are not a probability or possibility but rather a reality which would be recognized by persons of ordinary skill in the art.

The present claims embrace the patient population with coextensive pain and negative sensory phenomena.

Appellent's arguments concerning the doctrine of inherent anticipation have been fully considered and are not persuasive. The Examiner has carefully crafted the rejection based upon facts provided by Rowbotham et al. demonstrating a patient population with coextensive pain and 'negative sensory phenomena'. Treatment of one necessarily treats the other as explained in detail above. In other words, while numbness and other negative sensory phenomena may not be present in all patients, the Examiner has found a teaching where negative sensory phenomena are present and coextensive with the pain which meets the limitations of the instant claims because this patient population is not excluded by the instant claim language. Even Appellent admits on the record that negative sensory phenomena or numbness are not necesssarily present in patients presenting with post herpetic neuralgia (page 5, last paragraph of the Appeal Brief). Thus, Appellent acknowledges on the record that negative sensory phenomena or numbness can be present in patients presenting with post herpetic neuralgia otherwise Appellent would have stated negative sensory phenomena or numbness are not present in patients presenting with post herpetic neuralgia. Appellent asserts that the Examiner ignores teachings in Rowbotham et al. where, for example, "patients with severe pain had little, if any, sensory deficit…" (page 6 of the Appeal Brief). This argument supports the Examiner's position and destroys

Appellent's position because it is clear form this passage that Rowbotham et al. teaches that patients with pain also had sensory deficit as even a "little" would mean some sensory deficit.

Appellent once again attacks the MedlinePlus Medical Encyclopedia reference (A service from the National Institutes of Health) which clearly informs the reader that symptoms of neuralgia/postherpetic neuralgia include numbness. The Examiner has copied the relevant section below with Examiner added emphasis:

Symptoms

- Pain located anywhere, usually on or near the surface of the body
  - In the same location for each episode
  - Sharp, stabbing pain or constant, burning pain
- Pain along the path of a specific nerve

- Impaired function of affected body part due to pain, or muscle weakness due to motor nerve damage.
- Increased sensitivity of the skin or numbness of the affected skin area (feeling similar to a local anesthetic, such as a Novocaine shot)

Appellent merely asserts that the reference is in error without providing factual proof as certainly Rowbotham et al. supports the reference.

Appellent launches into another argument that post-herpetic neuralgia pain can occur without negative sensory phenomena. The Examiner has addressed this argument above. Appellent makes an erroneous conclusion that the patients in US '738 only had pain as a symptom. One cannot make such a sweeping statement unless all other symptoms, such as heat cold, gentle touch etc…, were examined and in this case they were not. As taught by Rowbotham et al., post herpatic neuralgia, patients "***demonstrated deficits in the perception of single gentle touches, pinprick, heat***

and cold which were greatest in the centre of the painful area and faded toward the boundary between involved and normal skin." (page 347, right column; Examiner added emphasis).

Appellent simply seems not to understand or grasp the fact that a certain population of neuralgia patients experience both pain and negative sensory phenomena and when a lidocaine patch is applied to the locus of pain one inherently performs the instant method and treats both the pain and negative sensory phenomena.

With respect to the 103(a) rejection, once again Appellent asserts that the MedlinePlus Medical Encyclopedia reference is improper and it is not a "universal fact". There is nothing wrong with the reference and it is a proper teaching in the art. Appellent can argue and argue but the fact is that the reference is a *bona fide* teaching in the art which aids in demonstrating that there is no allowable subject matter in the instant application. Appellent argues that the Examiner cannot have it both ways. The Examiner is the fact finder and the fact is that patients with postherpetic neuralgia can have as a symptom numbness. That much is clear and the Examiner's position has not changed.

Appellent re-visits the inherent anticipation arguments. The Examiner has responded in detail to these arguments above. Appellent argues that the MedlinePlus Medical Encyclopedia reference is improper because there can be no such thing as "inherent obviosness". The Examiner strongly disagrees. The principle of law states:

From MPEP 2131.01 III: Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date.

It is a universal fact that patients with postherpetic neuralgia have numbness as a symptom as shown by the cited references above. Appellent's arguments concerning the reference are simply not persuasive.

Appellent's argue unexpected results and direct the Examiner to [0018 and 0019] of the instant specification. The only apparently anecdotal example, as there is no experimental objective data for the Examiner to review, supports the Examiner's position that pain and numbness are coextensive. From [0018] (Examiner added emphasis):

> application of local anesthetics such as lidocaine can effectively treat NSP. For example, some diabetic neuropathy patients reported both pain relief and improved NSP, that is, the patients experienced pain relief, improvement of sensory loss (decreased numbness), and improved tactile response (they could better feel objects touching their skin). Thus the anesthetic as

Appellent argues no motivation or reasonable expectation of success. The Examiner strongly disagrees for the reasons provided in great detail above. Appellent argues that the claimed methods are more than the predictable use of prior art elements according to their established functions. The Examiner strongly disagrees for the reasons provided in great detail above.

Summary:

- Hind discloses treating postherpetic neuralgia patients with lidocaine patches at the site of pain;
- Rowbotham et al. teaches that postherpetic neuralgia patients have coextensive pain and negative sensory phenomena;

- Consequently treating a postherpetic neuralgia patient with lidocaine inherently treats the negative sensory phenomena;
- There is no objective data in the specification as filed; and
- Given the preponderance of evidence of record and lack of objective evidence to support Appellent, the Examiner can only conclude that there is no allowable subject matter.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ernst V Arnold/

Primary Examiner, Art Unit 1616

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